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THE				Filing Date	April 26, 2000				
STATEMENT BY APPLICANT				First Named Inventor	Richard B. Mazess				
				Group Art Unit	1644				
	(use as many she	ets as necessary	)	Examiner Name	Phuong N. Huynh				
Sheet	ı	of	5	Attorney Docket Number	017620-9277				

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.	
PNY	Barton, D. et al., "Synthetic Uses of Steroidal Ring & Diene Protection: 22,23-Dihydroergosterol," JCS Perkin I, (1976) pp. 821-826.	
	Beer, T. et al., "Weekly High-Dose Calcitriol and Docetaxel in Metastatic Androgen-Independent Prostate Cancer," <i>Journal of Clinical Oncology</i> , (Jan. 2003) 21:1:123-128.	
	Blazsek, I. et al. "Combined Differentiation Therapy in Myelodysplastic Syndrome with Retinoid Acid, 1α,25 Dihydroxyvitamin D <sub>3</sub> , and Prednisone," 16:4:259-264 (Abstract).	
	Brautbar, N. "Osteoporosis: Is 1,25-(OH)2D3 of Value in Treatment?" Nephron (1986) 44:161-166.	
	Braunwald, E. et al., <i>Harrison's Principles of Internal Medicine</i> : Part Eleven, "Disorders of Bone and Mineral Metabolism," Chapter 335, McGraw-Hill, New York, (1987) pp. 1860-1865.	
	Brown, J.P. et al., "Serum Bone Gala-Protein: A Specific Marker for Bone Formation in Postmenopausal Osteoporosis," <i>Lancet</i> , (1984) 1:1091-1093.	
	Caniggia, A. et al., "Effect of a Long-Term Treatment with 1,25-Dihydroxyvitamin D <sub>3</sub> on Osteocalcin in Postmenopausal Osteoporosis," Cacified Tissue Int., (1986) 38:328-332.	-
	Christiansen, C. et al., "Prevention of Early Postmenopausal Bone Loss: Controlled 2-Year Study in 315 Normal Females," <i>Europ J Clin Inves.</i> , (1980) 10:273-279.	
	Crump, D.R. et al., "(22S)-Hydroxyvitamin D <sub>4</sub> ," J.C.S. Perkins Trans. I, (1973) pp. 2731-2733.	
	Cho, Y.L. et al., "Combined Effects of 1,25-Dihydroxyvitamin D <sub>3</sub> and Platinum Drugs on the Growth of MCF-7 Cells," Cancer Research, (June 1991) 51:2848-2853.	
	Defacque, H. et al., "Different Combinations of Retinoids and Vitamin D <sub>3</sub> Analogs Efficiently Promote Growth Inhibition and Differentiation of Myelomonocytic Leukemia Cell Lines," <i>J. Pharmacology and Experimental Therapeutics</i> , (1994) 271:193-199.	
	DeLuca et al., "Synthesis, Biological Activity, and Metabolism of 22,23-3H-Vitamin D <sub>4</sub> ," Arch. Biochem, Biophys., (1968) 124:122-128.	
	Duda et al., "1,25-Dihydroxyvitamin D Stimulation Test for Osteoblast Function in Normal and Osteoporotic Postmenopausal Women," J. Clinic Inves., (1987) 79:1249-1253.	
	Endo, K. et al., "Effect of Combination Treatment with Vitamin D Analog (OCT) and a Bisphosphonate (AHPrBP) in a Nude Mouse Model of Cancer-Associated Hypercalcemia," <i>Journal of Bone and Mineral Research</i> , (1998) 13:9:1378-1383.	

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Complete if Known Substitute for form 1449B/PTO 09/402,636 **Application Number** INFORMATION DISCLOSURE Filing Date April 26, 2000 First Named Inventor Richard B. Mazess STATEMENT BY APPLICANT Group Art Unit 1644 (use as many sheets as necessary) Examiner Name Phuong N. Huynh Attorney Docket Number 017620-9277 Sheet

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	}
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.	
PAK	Foldes, J. et al., "Long Term Treatment with 1α (OH)D <sub>3</sub> for Postmenopausal Osteoporosis: Efficacy and Safety," Osteoporosis, (1987) 2:971-973.	
	Gallagher, J.C. et al., "Effects of Increasing Doses of 1\alpha-Hydroxyvitamin D <sub>2</sub> on Calcium Homeostasis in Postmenopausal Osteopenic Women," J. Bone Min. Res., (1994) 9:5:607-614.	
	Grab, W. Z. Physiol. Chem., (1936) 243:63-89.	
	Guidelines for the Clinical Evaluation of Drugs Used in the Treatment of Osteoporosis, HEW (FDA) 80-3094, (1979) pp. 5-6.	
	Hershberger, P. et al. "Calcitriol (1,25-Dihydroxycholecalciferol) Enhances Paclitaxel Antitumor Activity in Vitro and in Vivo and Accelerates Paclitaxel-induced Apoptosis," Clinical Cancer Research, (April 2001) 7:1043-1051.	
	Hoikka, V. et al., "Treatment of Osteoporosis with 1-Alpha-Hydroxycholecalciferol and Calcium," Acta. Med. Scand. (1980) 207:221-224.	/
	Holick, M.F., "Noncalcemic Actions of 1,25-Dihydroxyvitamin D <sub>3</sub> and Clinical Applications", <i>Bone</i> , (1995) 17:2:107S-110S.	
	Horst et al., "Quantitation of Vitamin D and its Metabolites and Their Plasma Concentrations in Five Species of Animals," Anal. Biochem., (1981) 116:189-203.	   
	Horst et al., "Discrimination in the Metabolism of Orally Dosed Ergocalciferol and Cholecalciférol by the Pig, Rat and Chick," <i>Biochem. J.</i> , (1982) 204:185-189.	
	Johnson, C. et al., "Vitamin D-related Therapies in Prostate Cancer," Cancer and Metastasis Review 21, (2002) pp. 147-158.	
	Kanis, J.A. et al., "Guidelines for Clinical Trials in Osteoporosis, A Position Paper of the European Foundation for Osteoporosis," Osteoporosis Int., (1991) 1:182-188.	
	Kim, S. et al., "Potentiation of 1,25-Dihydroxyvitamin D <sub>3</sub> -Induced Differentiation of Human Promyelocytic Leukemia Cells into Monocytes by Costunolide, a Germacranolide Sesquiterpene Lactone, <i>Biochem. Pharmacology</i> , (2002) 64:1233-1242.	
	Knutson, et al., "Metabolism of 1 α-Hydroxyvitamin D <sub>2</sub> to activated Dihydroxyvitamin D <sub>2</sub> Metabolites Decreases Endogenous 1α,25-Dihydroxyvitamin D <sub>3</sub> in Rats and Monkeys," <i>Endocrinology</i> , (1995) 136:11:4749-4753.	
//	Kocienski, P.J. et al., "Calciferol and its Relatives. A Synthesis of Vitamin D <sub>4</sub> ," J.C.S. Perkins I, (1979) pp. 1290-1293.	
V	Lam, H.Y. et al., Science, (1974) 486:1038-1040.	
Examiner	Date 1/1.1	

Signature Considered EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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STATEMENT BY APPLICANT  (use as many sheets as necessary)				First Named Inventor	Richard B. Mazess					
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			)	Examiner Name	Phuong N. Huynh					
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	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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PH	Majewski, et al., "Inhibition of Tumor Cell-Induced Angiogenisis by Retinoids, 1,25-Dihydroxyvitamin	
1700	D <sub>3</sub> and their Combination," Cancer Letters, (1993) 75:35-39.  Martin and DeLuca, "Calcium Transport," Am. J. Physiol., 216:1352-1359.	
	Mathias, C.J. et al., "Tumor-Selective Radiopharmaceutical Targeting Via Receptor-Mediated Endocytosis of Gallium-67-Deferoxamine-Folate," J. Nucl. Med. (1996), 37(6):1003-1008.	
	McDonald, F.G., "The Multiple Nature of Vitamin D," J. Biol. Chem. 114, (1936) 1xv.	
	Merck Index, S. Budavari (ed.), 11th ed., Merck & Co., Rahway, N.J. (1989) pp. 1579, #9930	
	Moffatt, K. et al., "1α,25-Dihydroxyvitamin D <sub>3</sub> and Platinum Drugs Act Synergistically to Inhibit the Growth of Prostate Cancer Cell Lines," Clinical Cancer Research, (March 1999) 5:695-703.	
	Muindi, J. et al., "Pharmacokinetics of High-Dose Oral Calcitriol: Results From a Phase 1 Trial of Calcitriol and Paclitaxel," Clinical Pharmacology & Therapeutics, (Dec. 2002) pp. 648-659.	
	Nemeto, H. et al., "A Stereoselective Synthesis of 1 α - Hydroxy-Vitamin D <sub>3</sub> ," CHEMISTRY LETTERS, (1985) 8:1131-1132.	
	Paaren et al., "Direct C(1) Hydroxylation of Vitamin D <sub>3</sub> and Related Compounds," J. Org. Chem., (1980) 45:3253.	
	Packman, K. et al. "Combination Treatment of MCF-7 Xenografts with the Vitamin D <sub>3</sub> Analog EB1089 and Antiestrogens," (Vitamin D Endocrine Workshop, Nashville, TN May 27-June 1, 2000) pp. 511-514.	
	Podenphant, J. et al., "Serum Bone Gla Protein and Other Biochemical Estimates of Bone Turnover in Early Postmenopausal Women During Prophylactic Treatment for Osteoporosis," <i>Acta Med Scand</i> , (1985) 218:329-333.	
<del>-   -  </del>	Physician's Desk Reference, Edition 43:1746-1748.	
	Pouilles, J.M. et al., "Prevention of Early Postmenopausal Bone Loss with 1α-Hydroxy Vitamin D <sub>3</sub> , A Three-Year Prospective Study," Clin Rheumatol. 11, 4 (1992) pp. 492-497.	
	Ravid, A. et al., "1,25-Dihydroxyvitamin D <sub>3</sub> Enhances the Susceptibility of Brease Cancer Cells to Doxorubicin-induced Oxidative Damage," Cancer Research, (February 15, 1999) 59:862-867.	
	Reeve, L.E. et al., "Biological Activity of $1\alpha$ -hydroxy Vitamin D <sub>2</sub> in the Rat," Arch. Biochem. Biophys. (Feb. 1978) 186:1:164-167.	
	Sato, F. et al., "Biological Activity of 1α,25-Dihydroxyvitamin D Derivatives – 24-epi-1α,25-Dihydroxyvitamin D-2 and 1α,25-Dihydroxyvitamin D-7," Biochim. Biophys. Acta, (1991) 1091:188-192.	

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	 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.	
Puk	 Shiraki, M. et al., Endocrinol. Japan, (1985) 32:305-315.	_
	Siwinska, A. et al. "Potentiation of the Antiproliferative Effect in Vitro of Doxorubicin, Cisplatin and Genistein by New Analogues of Vitamin D," Anticancer Research, (2001) 21:1925-1929.	
	 Sjoden et al., "Effects of 1 OHD <sub>2</sub> on Bone Tissue," Acta. Endocrinol. (Copenh.) (Aug. 1984) 16:4:564-568.	
	 Sjoden, G. et al., "Antirachitic Activity of 1α-Hydroxyergocalciferol and 1α-Hydroxycholecalciferol in Rats," J. Nutr., (1984) 114:2043-2046.	
	 Sjoden, G. et al., "1α-Hydroxyvitamin D <sub>2</sub> is Less Toxic than 1α-Hydroxyvitamin D <sub>3</sub> in the Rat," <i>Proc. Soc. Exp. Biol. Med.</i> , (1985) 178:432-436.	
	 Skowronski et al., "Vitamin D and Prostate Cancer: 1,25 Dihydroxyvitamin D <sub>3</sub> Receptors and Actions in Human Prostate Cancer Cell Lines," <i>Endocrinology</i> , (1993) 132:1952-1960.	
	 Slapak, C. et al., "Treatment of Acute Myeloid Leukemia in the Elderly with Low-Dose Cytarabine, Hydroxyurea, and Calcitriol," <i>Amer. J. Hematology</i> , (1992) 41:178-183.	
	 Sommerfeldt et al., "Metabolism of Orally Administered [ <sup>3</sup> H]Ergocalciferol and [ <sup>3</sup> H]Cholecalciferol by Dairy Calves," J. Nutr., (1983) 11:2595-2600.	
	 Song, X.D. et al., "Bryostatin-1 and 1α,25-Dihydroxyvitamin D <sub>3</sub> Synergistically Stimulate the Differentiation of NB4 Acute Promyelocytic Leukemia Cells," <i>Leukemia</i> , (1999) 13:275-281.	
	 Studzinski, G. et al., "Potentiation by 1-α25- Dihydroxyvitamin D <sub>3</sub> of Cytotoxicity to HL-60 Cells Produced by Cytarabine and Hydroxyurea," J. National Cancer Inst., (April 1986) 76:4:641-648.	
	Strugnell et al., "Metabolism of a Cyclopropane-Ring-Containing Analog of 1\alpha-Hydroxyvitamin D <sub>3</sub> in a Hepatocyte Cell Model," <i>Biochem. Pharm.</i> , (1990) 40:333-341.	
-	Strugnell et al., "1 $\alpha$ ,24(S)-Dihydroxyvitamin D <sub>2</sub> : a biologically active product of 1 $\alpha$ -hydroxyvitamin D <sub>2</sub> made in the human hepatoma, Hep3B," <i>Biochem. J.</i> , (1995) 310:233-241.	
	Suzuki, Y. et al., "The Enhancement of the Chemotherapeutic Effects on Human Prostate Cancer Cell – The Combination with the Growth Factor Interaction Inhibitor (Suramin)," Acta Urologica (1993) 12:1215-1220, (Abstract).	
	Swami, S. et al. "1α,25-Dihydroxyvitamin D <sub>3</sub> Down-Regulates Estrogen Receptor Abundance and Suppresses Estrogen Actions in MCF-7 Human Breast Cancer Cells," <i>Clinical Cancer Research</i> , (Aug. 2000) 6:3371-3379.	
$\sqrt{}$	Tachibana, Y. (Nisshin Flour Milling Co.), "Preparation of 1Beta-Hydroxyvitamin D <sub>2</sub> and D <sub>3</sub> ," CHEMICAL ABSTRACTS, (1990) 113:1:6688 Col. 2 Abstract No. 6683y.	

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71/2	Tanaka, Y. et al., Endocrinology (1973) 92:417-422.
PAK	Torres, R. et al., "Etoposide Stimulates 1,25-Dihydroxyvitamin D <sub>3</sub> Differentiation Activity, Hormone Binding and Hormone Receptor Expression in HL-60 Human Promyelocytic Cells, <i>Molecular and Cellular Biochemistry</i> , (2000) 208:157-162.
	Tsuji, M. et al., "Synthesis of 22,23-Dihydro-1α,25-Dihydroxyvitamin D <sub>2</sub> and its 24R-Epimer, New Vitamin D <sub>2</sub> Derivatives," Bull. Chem. Soc. Jpn., (1990) 63:8:2233-2238.
	Wang, Q. et al., "1,25-Dihydroxyvitamin D <sub>3</sub> and All-trans-Retinoic Acid Sensitize Breast Cancer Cells to Chemotherapy-induced Cell Death," Cancer Research, (April 2000) 60:2040-2048.
	Wang, X. et al., "Inhibition of p38 MAP Kinase Activity Up-Regulates Multiple MAP Kinase Pathways and Potentiates 1,25-Dihydroxyvitamin D <sub>3</sub> -Induced Differentiation of Human Leukemia HL60 Cells," Experimental Cell Research, (2000) 258:425-437.
	Wientroub, S. et al. "The Dichotomy in the Effects of 1,25 Dihydroxy Vitamin D <sub>3</sub> and 24, 25 Dihydroxy Vitamin D <sub>3</sub> on Bone Gamma-Carboxyglutamic Acid-Containing Protein in Serum and Bone in Vitamin D-Deficient Rats," <i>Calcif, Tissue Int.</i> , (1987) 40:166-172.
	Windaus, A. et al., "Uber das Krystallisierte Vitamin D <sub>4</sub> ," Z. Physiol. Chem., (1937) 247:185-188.
	Yu, W. et al., "Enhancement of 1,25- Dihydroxyvitamin D <sub>3</sub> - Mediated Antitumor Activity with Dexamethasone," J. National Cancer Inst., (January 1998) 90:2:134-141.
-	Zerwekh et al., "Short-Term 1,25-Dihydroxyvitamin D <sub>3</sub> Administration Raises Serum Osteocalcin in Patients with Postmenopausal Osteoporosis," <i>J. Clin. Endocrinol. Metabol</i> , (1985) 60:615-617.

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Complete if Known form 1449/PTO 09/402,636 **Application Number** DISCLOSURE STATEMENT BY April 26, 2000 **APPLICANT** Filing Date First Name Inventor Richard B. Mazess Group Art Unit 1644 (use as many sheets as necessary) Phuong N. Huynh **Examiner Name** 017620-9277 Attorney Docket Number Sheet

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1	Japan	5320127	Nisshin Flour Milling Co.	09/29/93		
	Japan	6025039	Kurary Co. Ltd.	02/01/94		
	Japan	62000033	General Hospital	10/15/86		
	EP	0197514	General Hospital	10/15/86		
	EP	0390097	Nisshin Flour Milling Co.	10/03/90		
	EP	0562497	Nisshin Flour Milling Co.	09/29/93		
	EP	0503630	Kuraray Co. Ltd.	09/16/92		
	EP	0664287	Duphar International	07/26/95		
	PCT	WO 84/04527	Wisconsin Alumni Research Foundation	11/22/84		
	PCT	WO 87/00834	Leo Pharmaceutical Products, Ltd.	02/12/87		
	PCT	WO 90/10620	Wisconsin Alumni Research Foundation	09/20/90	131	
	PCT	WO 92/05130	Lunar Corporation	04/02/92		
	PCT	WO 92/12165	Lunar Corporation	07/23/92		
	PCT	WO 92/14493	Capelli & Paaren	09/03/92		
	PCT	WO 92/21355	Procter & Gamble	12/10/92		
	PCT	WO 93/14763	Lunar Corporation	08/05/93		
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# **影**LECTRONIC INFORMATION DISCLOSURE STATEMENT

Element Version v18

Stylesheet Version v18.0

Title of Invention TARGETED THERAPEUTIC DELIVERY OF VITAMIN D COMPOUNDS

Application Number:

09/402636

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Confirmation Number:

6232

First Named Applicant:

Richard Mazess

Attorney Docket Number: 0176209277

Examiner:

Phuong H. Huynh

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### **US Patent Documents**

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind Class Subclass
PIK	1	2383446	1941-06-046	Calcott et al	
	2	3697559	7972740-10	DeLuca et al	
	3	3741996	19/3-06-26	DeLuca et al	
	4	3907843	1975-09-23	DeLuca et al	
V	5	4160803	1979-07-10	Potts	
				,	<u> </u>

DYK	6	4195027	1980-03-25	DeLuca et al
	7	4202829	1980-05-13	DeLuca et al
	8	4234495	1980-11-18	DeLuca et al
	9	4260549	1981-04-07	DeLuca et/al
	10	4292250	1981-09-29	DeLuca et al
	11	4362710	1982-12-07	Watanabe
	12	4508651	1985-04-02	Baggiolini et al
	13	4554106	1985-11-19	De Luca et al
	14	4555364	1985-11-19	DeLuca et al
	15	4588716	1986-05-13	DeLuca et al
	16	4661294	1987-04-28	Holick et al
	17	4689180	1987-08-25 /	DeLuca et al
	18	4698328	1987/\0-06	Neer et al
	19	4717721	1988-01-25	DeLuca et al
	20	4833125	1989-05-23	Neer et al
	21	4866048	1989-09-12	Calverley et al
	22	4902481	1990-02-20	Clark et al
	23	5063221	1991-11-05	Nishii et al
	24	5104864	992-04-14	DeLuca et al
	25	5141719	1992-08-25	Fernwood et al
	26	5157135	1992-10-20	Tsuji et al
	27	5205989/	1993-04-27	Aysta
	28	521952/8	1993-06-15	Clark
	29	5232836	1993-08-03	Bouillon et al
	30	5264184	1993-11-23	Aysta et al
	31	5264618	1993-11-23	Felgner et al
	32	5334740	1994-08-02	Takahashi et al
	33	5338532	1994-08-16	Tomalia et al
Ħ	34	5372996	1994-12-13	Labrie ´
	35	5403831	1995-04-04	DeLuca et al
H	36	5417923	1995-05-23	Bojanic et al
	<b>\$</b> 7	5488120	1996-01-30	Knutson et al
	38	5527524	1996-06-18	Tomalia et al

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Pik	39	5554386	1996-09-10	Groman et al
	40	5576309	1996-11-19	Tamura et al
	41	5597575	1997-01-28	Breitbarth
	42	5602116	1997-92-11	Knutson et al
	43	5614513	1997-03/28	Knutson et al
	44	5637742	997-06-10	Valles et al
	45	5661 <b>025</b> /	1997-08-26	Szoka, Jr. et al
	46	5691328	1997-11-25	Peterson et al
	47	5739271	1998-04-14	Sridhar et al
	48	\$795882	1998-08-18	Bishop et al
	49	6309666	2001-10-30	Hatano et al
	50	6521608	2003-02-18	Henner et al

## Remarks

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This is the first of two (2) electronic submissions. Both electronic submissions are being filed simultaneously with a paper IDS submission of foreign patents/applications and non-patent references. All are considered to be part of the same, single IDS. Citation of these references is respectfully requested. No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate. A check for \$180 is included with the paper copy submission.

## Signature

Examiner Name	Date
Dh Na	11/15/04

# **ELECTRONIC INFORMATION DISCLOSURE STATEMENT**

MADULTONIC Version v18

Stylesheet Version v18.0

MAR 1 5 2004

Title of Invention TARGETED THERAPEUTIC DELIVERY OF VITAMIN D **COMPOUNDS** 

Application Number:

09/402636

\*09/402636\*

Confirmation Number:

6232

First Named Applicant:

Richard Mazess

Attorney Docket Number: 0176209277

Examiner:

Phuong H. Huynh

Search string:

(6537982).pn.

### **US Patent Documents**

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
Pur	1 <	6537982	2000/03-25	Bishop et al			

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Electronic Version v18 Stylesheet Version v18.0

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Search string:

(2383446 or 3697559 or 3741996 or 3907843

or 4160803 or 4195027 or 4202829 or 4234495 or 4260549 or 4292250 or 4362710 or 4508651 or 4554106 or 4555364 or 4588716 or 4661294 or 4689180 or 4698328 or 4717721 or 4833125 or 4866048 or 4902481 or 5063221 or 5104864

or 5141719 or 5157135 or 5205989 or 5219528 or 5232836 or 5264184 or 5264618 or 5334740 or 5338532 or 5372996 or 5403831 or 5417923 or 5488120 or 5527524 or 5554386 or 5576309

or 5597575 or 5602116 or 5614513 or 5637742 or 5661025 or 5691328 or 5739271 or 5795882

or 6309666 or 6521608 ).pn.

### **US Patent Documents**

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	init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
	PM	1	2383446	1941-06-04	Calcott et al			
		2	3697559	1972-10-10	DeLuca et al			
		3	3741996	1973-06-26	DeLuca et al			
		4	3907843	1975-09-23	DeLuca et al	,		
		5	4160803	1979-07-10	Potts			
8		6	4195027	1980-03-25	DeLuca et al			
		7	4202829	1980-05-13	DeLuca et al			·
		8	4234495	1980-11-18	DeLuca et al			
	V	9	4260549 <	1981-04-07	DeLuca et al			

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Page 1 of 3

104	10	4292250	1981-09-29	DeLuca et al
	11	4362710	1982-12-07	Watanabe
	12	4508651	1985-04-02	Baggiolini et al
	13	4554106 <	1985-11-19	DeLuca et al
	14	4555364 /	1985-11-19	DeLuca et al
	15	4588716 <	1986-05-13	DeLuca et al
	16	4661294	1987-04-28	Holick et al
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	26	5157135 /	1992-10-20	Tsuji et al
	27	5205989 /	1993-04-27	Aysta
	28	5219528 /	1993-06-15	Clark
	29	5232836	1993-08-03	Bouillon et al
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	35	5403831	1995-04-04	DeLuca et al
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	42	5602116 ′	1997-02-11	Knutson et al
	43	5614513	1997-03-25	Knutson et al
	44.	5637742 <	1997-06-10	Valles et al
	45	5661025	1997-08-26	Szoka, Jr. et al
APP_ID	)=09402636	N. Je		11/15/04

Page 2 of 3

PM	46	5691328	1997-11-25	Peterson et al
	47	5739271	1998-04-14	Sridhar et al
	48	5795882	1998-08-18	Bishop et al
	49	6309666	2001-10-30	Hatano et al
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Title of Invention TARGETED THERAPEUTIC DELIVERY OF VITAMIN D
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**Application Number:** 

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**Richard Mazess** 

Attorney Docket Number: 0176209277

0470000077

Examiner:

Phuong H. Huynh

Search string:

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init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
PART -	1	6537982	2003-03-25	Bishop et al			

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John N Van	11/15/04